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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/519,804   | 05/19/2006  | Francis P. Kuhadja   | P71523US/37049 00003 | 7358             |
| 85938  | 7590        | 03/26/2010           |                      |                  |
| Fox Rothschild LLP<br>Phila, Biotech Group<br>2000 Market Street<br>Philadelphia, PA 19103 |             |                      |                      |                  |
| EXAMINER   |             |                      |                      |                  |
| RAHMANI, NILOOFAR  |             |                      |                      |                  |
| ART UNIT   |             | PAPER NUMBER         |                      |                  |
| 1625   |             |                      |                      |                  |
| MAIL DATE  |             | DELIVERY MODE        |                      |                  |
| 03/26/2010   |             | PAPER                |                      |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/519,804

**Applicant(s)**

KUHADJA ET AL.

**Examiner**

NILOOFAR RAHMANI

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 18-20, 23-63, 66, 67 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 18-19, 23-31, 33, 35-67, 71-73 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 and 34 is/are allowed.
- 6) ☒ Claim(s) 15, 16, 32, 69 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-16, 18-20, 23-63, 66-67, 69-73 are pending and claims 17, 21-22, 64-65, 68 are cancelled in the instant application.

Claims 15-16, 20, 32, 34, 69-70 drawn to compounds and pharmaceutical composition of formula (V) and (VII) are examined. Claims 1-14, 18-19, 23-31, 33, 35-67 and 71-73 remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

2. The rejection of claims 15-16 and 32 under 103(a) over Asano et al., and Drioli et al., and Zhang et al. is withdrawn in view of applicant's amendment.

3. The rejection of claims 15-16 and 32 under 102(b) over Kilminster et al. US 4753871 and Azevedo et al. and Kamikawa et al. and Haerdi et al. is withdrawn in view of applicant's amendment.

4. The rejection of claims 20 and 34 under 103(a) over Cavallito et al. and Pohmakotr et al. is withdrawn in view of applicant's amendment.

5. ***New Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

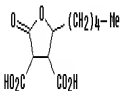
Claims 15-16, 32, 69-70 are rejected under 103(a) as being unpatentable over De Azevedo et al., Journal of Organic Chemistry (1992), 57(170, 4567-9.

Determination of the scope and content of the prior art (MPEP §2141.01)

De Azevedo et al. disclosed analogous compounds, which from the STN search is

**RN 142188-52-1**

**CN 3,4-Furandicarboxylic acid, tetrahydro-2-oxo-5-pentyl-**



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claim and the prior art compound is that the instant claim replaces C<sub>5</sub>H<sub>11</sub> of the prior art compound with C<sub>6</sub>H<sub>12</sub>.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of De Azevedo et al. to obtain the instant compound.

A compound that differs only in molecular arrangement from the compounds disclosed in the prior art and which for which no unexpected properties of this compound are disclosed in the specification is unpatenable, *Ex parte KRUEGER AND HAYES*, 121 USPQ 420, *In re NORRIS*, 84 USPQ 458, *In re Hass* 60 USPQ 552, which found a *prima facie* case of obviousness of 1-chloro-1-nitrobutane over 1-chloro-1-nitroisobutane taught in the prior art, *Ex parte Ulliot*, 103 USPQ 185, which found a *prima facie* case of obviousness of 2-oxo-quinolines over a 1-oxo-isoquinoline taught in the prior art, *In re FINLEY*, 81 USPQ 383, which found a *prima facie* case of obviousness of 2-ethyl hexyl salicylate over octyl salicylate taught in the prior art.

Compounds that differ only by the presence or absence of an extra methylene group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologues. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methylene groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148, *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ; *In re Druey*, 138 USPQ 39.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

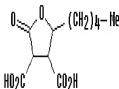
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**6. Allowable Subject Matter**

Claims 20 and 34 are patentable over De Azevedo et al., Journal of Organic Chemistry (1992), 57(170, 4567-9, which includes the exemplified compound:

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**CN 3,4-Furandicarboxylic acid, tetrahydro-2-oxo-5-pentyl-**



, which has a  $-(CH_2)_4$ -Me substituted furan ring. At the position corresponding to  $-(CH_2)_4$ -Me, the instant application requires that this position must be C<sub>16</sub>-C<sub>20</sub> alkyl. Therefore, the claims are free of prior art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

03/18/2010

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625